

Application No. 09/436,455
Amendment Dated January 22, 2004
Reply to Office Action mailed September 24, 2003
Page 16

REMARKS

Request for Notice of Cited Reference (PTO-892)

Applicant notes that the reference cited by the Office Action, U.S. Patent No. 6,014,589 to Farley et al. was not found in the PTO-892, Notice of Cited References. Applicant respectfully requests appropriate listing of the reference in the subject application.

Amendment to Claims

Applicant amended claims 1, 3-5, 11, and 83. Claim 95 is added. Claim 77 is cancelled. Accordingly, claims 1-13, 18-75, 79-95 are currently pending. Applicant believes that no new matter is entered by way of these amendments.

Applicant's attorney wishes to thank the Examiner for the indication that claim 53 would be otherwise allowable if re-written in independent form including all limitations of the base and intervening claims. Claim 53 is presented in independent form as newly added claim 95.

35 U.S.C. §112 - I

The Office Action rejected claims 1-13, 18-75, 77, 79-83, and 85-92 under 35 U.S.C. §112, 1st paragraph, as failing to comply with the written description requirement. The Office Action asserts that "there is no description as to how to extract the temperature signal from a temperature sensor which is in electrical communication with the conductive leg" and there is no disclosed electrode that generates RF energy. Applicant disagrees.

With regard to the temperature signal: the claims recite "a temperature detecting element attached to one of the legs wherein the temperature detecting element is in electrical communication with the leg." On page 30, the application recites, "[e]xamples of temperature detecting elements include thermocouples, infrared sensors, thermistors,

Application No. 09/436,455
Amendment Dated January 22, 2004
Reply to Office Action mailed September 24, 2003
Page 17

resistance temperature detectors (RTDs), or any other apparatus capable of detecting temperatures or changes in temperature." These devices are well known by those skilled in art.

One skilled in the art would understand that a thermistor is a thermally sensitive resistor whose primary function is to exhibit a change in electrical resistance with a change in body temperature, thermocouples are pairs of dissimilar metal wires joined at least at one end, which generate a net thermoelectric voltage between the open pair according to the size of the temperature difference between the ends. One skilled in the art will certainly understand the principles of these devices and how to determine a temperature measurement from these devices.

Furthermore, on page 30 the application recites "FIG. 5M illustrates a variation of the invention having thermocouple leads 139 attached to a leg 106 of the device. The leads may be soldered, welded, or otherwise attached to the leg 106. This variation of the invention shows both leads 139 of the thermocouple 137 attached in electrical communication to a leg 106 at separate joints 141. In this case, the temperature sensor is at the surface of the leg. This variation provides in case either joint becomes detached, the circuit will be open and the thermocouple 137 stops reading temperature. The device may also include both of the thermocouple leads as having the same joint."

The application provides sufficient description such that one skilled in the art will conclude that the inventors had possession of the invention as claimed. It is well established in U.S. patent law that the patent application does not require detailed procedures for making the invention. All that is required is that those skilled in the art can make and use the invention given the disclosure in the patent application. The process of extracting a temperature signal from a temperature detecting element that is in electrical communication with a conductive leg is well understood in the art.

With regard to the disclosure of an electrode that generates RF energy, applicant amended claims 3-5, and 11 for clarity. Page 20 of the application recites that "[t]hese devices can be used for delivering radio frequency in either a monopolar or a bipolar manner or for delivering other energy to the tissue, such as conducted heat energy from

Application No. 09/436,455
Amendment Dated January 22, 2004
Reply to Office Action mailed September 24, 2003
Page 18

resistively heated elements. As shown in FIG. 4, for monopolar energy delivery, one or more electrodes of the treatment device are connected to a single pole of the energy source 32 and an optional external electrode 44 is connected to an opposite pole of the energy source. For bipolar energy delivery, multiple electrodes are connected to opposite poles of the energy source 32 and the external electrode 44 is omitted. Naturally, the external electrode 44 depicted in FIG. 4, is not required in the case of bipolar energy delivery."

Based on the above, applicant requests withdrawal of this rejection.

35 U.S.C. §112 - II

The Office Action rejected claims 73, 77, and 83-94 under 35 U.S.C. §112, 1st paragraph, as failing to comply with the written description requirement.

Applicant cancelled claim 77. Claim 83 is amended to correct a typographical error. "Each electrically conductive member" is amended to "each electrically conductive leg."

Applicant believes that the above amendments address this rejection.

35 U.S.C. §102

The Office Action rejected claims 1-8, 10-13, 18-22, 24, 30, 44-52, 57-60, 62, 70, 71, and 74 under 35 U.S.C. §102(e) as being anticipated by Farley et al. (U.S. Patent no. 6,014,589). Applicant disagrees.

Claim 1 recites the second end of the legs being fixedly attached to the distal joint.

In contrast, the Farley device recites the electrode arms as "free to move within slots 46 formed in the distal tip 34" (see Farley, col. 7, lines 57-59.) Starting at column 8, line 66, Farley teaches that "As [vein] the wall shrunk, it applied force against the

Application No. 09/436,455
Amendment Dated January 22, 2004
Reply to Office Action mailed September 24, 2003
Page 19

electrodes causing the electrode arms 26 to contract. Because the electrode arms 26 are mounted with their distal ends free to move, as shown in FIGS. 4, 5, and 6, the electrode arms freely contracted as the vein wall shrunk. Upon reaching the diameter set by the stent arms 28, the vein stopped shrinking and the electrode arms stopped contracting.”

In view of the above, because Farley fails to anticipate all of the elements of claim 1, applicant believes the claims are allowable over Farley and requests withdrawal of this rejection.

35 U.S.C. §103

Re: All claims

The Office Action rejected claims 1-13, 18-30, 35-43, 54-56, 61, 63-70, 72-75, 77, and 79-94 under 35 U.S.C. §103(a) as being unpatentable over Farley in combination with Burnside et al. (U.S. Patent No. 6,071,281.) Applicant disagrees.

The Office Action fails to establish a proper *prima facie* case of obviousness with respect to this rejection. It is well established that the fact that references can be combined is not sufficient to establish a *prima facie* case of obviousness unless the known art also suggests the desirability of the combination. Also, the fact that a modification is within the capabilities of one of ordinary skill in the art is not sufficient by itself to establish a *prima facie* case of obviousness without some objective reason to combine the teachings. Applicant refers to MPEP §2143.01. Applicant notes that the Office Action fails to cite any motivation or objective reason for the combination of Farley and Burnside. In view of this, applicant requests the withdrawal of the rejection with respect to claims 1-13, 18-30, 35-43, 54-56, 61, 63-70, 72-75, 77, and 79-94

Re: Claim 1

With respect to the rejection of claim 1, as previously noted, Farley fails to teach all of the requirements of claim 1. At the very least, the electrode arms in Farley are free to move within slots formed in the distal tip of the device. Applicant notes that any

Application No. 09/436,455
Amendment Dated January 22, 2004
Reply to Office Action mailed September 24, 2003
Page 20

suggestion to modify this feature of the Farley device would render the device unsuitable for its expressly stated purpose of allowing the electrode arms to collapse given shrinking tissue. Based on this reason alone, applicant believes that the Office Action fails to establish a proper *prima facie* case with regard to claim 1 and all claims dependent therefrom.

Re: Claim 26

With respect to the rejection of claim 26: Farley teaches that "one or more of the electrodes 24 may comprise a thermocouple." Applicant refers to the specification and drawings of Farley which clearly show that the electrodes are located on an outside of the legs of the device. The Office Action fails to provide any objective reason or motivation as to why one would modify Farley to place the thermocouple on the inside of any of the legs. The Office Action's modification of Farley contradicts the teachings of Farley. Therefore, the Office Action fails to establish a proper *prima facie* case of obviousness and this rejection should be withdrawn.

Re: Claim 39

With respect to the rejection of claim 39, for the reasons stated above, Farley requires the electrode legs to be free to move within the distal tip. To use an adhesive to fixedly attach the legs to the distal tip of the device would render the modified device unsuitable for its intended purpose. Accordingly, this rejection is improper and applicant requests its withdrawal.

Re: Claims 63 and 83

With respect to the rejection of claims 63 and 83, applicant disagrees that the basis for the rejection is found in Burnside. Applicant is unable to find any teaching in Burnside regarding a wire carrying current that could modify Farley to render applicant's claims 63 and 83 unpatentable. Secondly, the Office Action fails to establish a *prima facie* case with regard to this combination of Burnside and Farley.

The Office Action states that Burnside teaches "a wire carrying current" and refers to figure 55 of Burnside. Claim 63 requires a wire that is configured to move the expandable portion and also requires the wire to provide a current. Claim 83 requires an

Application No. 09/436,455
Amendment Dated January 22, 2004
Reply to Office Action mailed September 24, 2003
Page 21

electrically conductive member that terminates at the distal tip, and is in electrical communication with the legs to deliver current to the legs. This electrically conductive member is also moveable relative to the proximal joint to permit deflection of the conductive legs.

In figure 55 of Burnside, the inner portions 232 of the spline legs L1-L4 are independently moveable. They pass through lumens 242 in the inner element 238 of the base 26 and into the catheter body lumen 36 for attachment to control knobs 234 on a handle 18. The control knobs 234 allow a physician to independently change the flexure of the spline legs. (See Burnside, col. 25, line 46 through col. 26 line 12.) Therefore these spline legs provide control of the shape and flexure of the Burnside ablation element. Contrary to applicant's claims, Burnside explicitly teaches that separate "wires 58 associated with the electrode elements 28 carried by each leg L1-L4 pass through other lumens 244 in the inner element 238 (see Fig. 61.)" (Burnside col. 25, lines 50-53.) Clearly, from Fig. 61, which is a top section view of the base 26 of Fig. 55, the wires 58 are separate from the spline legs 232. The spline legs travel in lumens 242 that are separate from lumens 244 which carry the electrode wires 58. Applicant further notes that the outer spline legs 230 do not extend through the device, rather they "double back" and are wedged into the device. (See Burnside, col. 25, lines 43-45; also Burnside Figure 6B.)

It is clear that Burnside fails to teach a wire that meets the requirements of claim 63 and 83. Therefore, on this deficiency alone, this combination is improper.

Apart from the above, applicant submits that the Office Action does not establish a proper *prima facie* case of obviousness. For example, there is no teaching or suggestion to make the proposed modification and any such modification renders the Farley device unsuitable for its intended purpose.

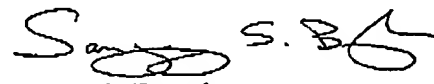
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Application No. 09/436,455
Amendment Dated January 22, 2004
Reply to Office Action mailed September 24, 2003
Page 22

SUMMARY

Applicant believes all outstanding issue raised in the previous Office Action are addressed herein and that the claims are in condition for allowance. If the Examiner believes a telephone conference would expedite prosecution of this application, please telephone the undersigned at (650) 428-1600.

Respectfully submitted,

A handwritten signature in black ink, appearing to read "Sanjay S. Bagade", with a stylized flourish at the end.

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